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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/071,838

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Jing Li

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,838	LI ET AL.	
	Examiner	Art Unit	
	Susan Ungar	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE one MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 08 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1-43 are pending in the application and are currently under prosecution.

It is noted that claim 30 has been withdrawn from consideration because it is dependent upon claim 8 and claims an antibody that selectively binds to the polypeptide of claim 8. However, claim 8 is not drawn to a polypeptide, but rather to tumor cancer cell types and therefore it is not possible to determine how to restrict the claimed invention. Upon amendment of the claim to clarify the limitations, the limitations of claim 30 will be appropriately restricted.

It is noted that claims 31 and 32 have been withdrawn from consideration because they are dependent upon claim 1 and claim an expression vector comprising the nucleic acid of claim 1. However, claim 1 is not drawn to a nucleic acid, but rather to a method of detecting cancer cells. Upon amendment of the claims to clarify the limitations, the limitations of claims 31 and 32 will be appropriately restricted.

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

3. Claim 1 as it is drawn to nucleic acid encoding SEQ ID NO:2 links inventions 1-4. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable

linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 1. Claims 1-9 are drawn to a method of detecting prostate cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

Group 2. Claims 1-9 are drawn to a method of detecting breast cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

Group 3. Claims 1-9 are drawn to a method of detecting lung cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

Group 4. Claims 1-9 are drawn to a method of detecting ovarian cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

4. Claim 1 as it is drawn to nucleic acid encoding SEQ ID NO:4 links inventions 5-8. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the

allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 5. Claims 1-9 are drawn to a method of detecting prostate cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

Group 6. Claims 1-9 are drawn to a method of detecting breast cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

Group 7. Claims 1-9 are drawn to a method of detecting lung cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

Group 8. Claims 1-9 are drawn to a method of detecting ovarian cancer cells in a biological sample comprising detecting a nucleic acid

molecule encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

5. Claim 1 as it is drawn to nucleic acid encoding SEQ ID NO:6 links inventions 9-12. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 9. Claims 1-9 are drawn to a method of detecting prostate cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 10. Claims 1-9 are drawn to a method of detecting breast cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 11. Claims 1-9 are drawn to a method of detecting lung cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 12. Claims 1-9 are drawn to a method of detecting ovarian cancer cells in a biological sample comprising detecting a nucleic acid molecule encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

6. Claim 10 as it is drawn to SEQ ID NO:2 links inventions 13-16. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 13. Claims 10-15 are drawn to a method of detecting prostate cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 14. Claims 10-15 are drawn to a method of detecting breast cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 15. Claims 10-15 are drawn to a method of detecting lung cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 16. Claims 10-15 are drawn to a method of detecting ovarian cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

7. Claim 10 as it is drawn to SEQ ID NO:4 links inventions 17-20. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 17. Claims 10-15 are drawn to a method of detecting prostate cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 18. Claims 10-15 are drawn to a method of detecting breast cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 19. Claims 10-15 are drawn to a method of detecting lung cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 20. Claims 10-15 are drawn to a method of detecting ovarian cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

8. Claim 10 as it is drawn to SEQ ID NO:6 links inventions 21-24. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 10. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d

1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 21. Claims 10-15 are drawn to a method of detecting prostate cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 22. Claims 10-15 are drawn to a method of detecting breast cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 23. Claims 10-15 are drawn to a method of detecting lung cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 24. Claims 10-15 are drawn to a method of detecting ovarian cancer cells in a biological sample comprising detecting overexpression of SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

9. Claim 16 as it is drawn to SEQ ID NO:2 links inventions 25-28. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of

the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 25. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of prostate cancer cells in a biological sample comprising detecting SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 26. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of breast cancer cells in a biological sample comprising detecting SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 27. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of lung cancer cells in a biological sample comprising detecting SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 28. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of ovarian cancer cells in a biological sample comprising detecting SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 7.1.

10. Claim 16 as it is drawn to SEQ ID NO:4 links inventions 29-32. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims

of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 29. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of prostate cancer cells in a biological sample comprising detecting SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 30. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of breast cancer cells in a biological sample comprising detecting SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 31. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of lung cancer cells in a biological sample comprising detecting SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 32. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of ovarian cancer cells in a biological sample comprising detecting SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 7.1.

11. Claim 16 as it is drawn to SEQ ID NO:6 links inventions 33-36. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 33. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of prostate cancer cells in a biological sample comprising detecting SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 34. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of breast cancer cells in a biological sample comprising detecting SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 35. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of lung cancer cells in a biological sample comprising detecting SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

Group 36. Claims 16-19 are drawn to a method of monitoring efficacy of treatment of ovarian cancer cells in a biological sample comprising detecting SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 7.1.

12. Claim 20 as it is drawn to nucleic acid encoding SEQ ID NO:2 links inventions 37-40. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 20. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise

including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 37. Claims 20 are drawn to a method of monitoring efficacy of treatment of prostate cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

Group 38. Claims 20 are drawn to a method of monitoring efficacy of treatment of breast cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

Group 39. Claims 20 are drawn to a method of monitoring efficacy of treatment of lung cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

Group 40. Claims 20 are drawn to a method of monitoring efficacy of treatment of ovarian cancer cells in a biological sample comprising detecting

nucleic acid encoding SEQ ID NO:2 or a variant thereof, classified in Class 435, subclasses 6.

13. Claim 20 as it is drawn to nucleic acid encoding SEQ ID NO:4 links inventions 41-44. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 20. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 41. Claims 20 are drawn to a method of monitoring efficacy of treatment of prostate cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

Group 42. Claims 20 are drawn to a method of monitoring efficacy of treatment of breast cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

Group 43. Claims 20 are drawn to a method of monitoring efficacy of treatment of lung cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

Group 44. Claims 20 are drawn to a method of monitoring efficacy of treatment of ovarian cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:4 or a variant thereof, classified in Class 435, subclasses 6.

14. Claim 20 as it is drawn to nucleic acid encoding SEQ ID NO:6 links inventions 45-48. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 16. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 45. Claims 20 are drawn to a method of monitoring efficacy of treatment of prostate cancer cells in a biological sample comprising detecting

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nucleic acid encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 46. Claims 20 are drawn to a method of monitoring efficacy of treatment of breast cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 47. Claims 20 are drawn to a method of monitoring efficacy of treatment of lung cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 48. Claims 20 are drawn to a method of monitoring efficacy of treatment of ovarian cancer cells in a biological sample comprising detecting nucleic acid encoding SEQ ID NO:6 or a variant thereof, classified in Class 435, subclasses 6.

Group 49. Claims 21-26 are drawn to a polynucleotide encoding SEQ ID NO:2/SEQ ID NO:1, classified in Class 536, subclass 23.1.

Group 50. Claims 21-26 are drawn to a polynucleotide encoding SEQ ID NO:4/SEQ ID NO:3, classified in Class 536, subclass 23.1.

Group 51. Claims 21-26 are drawn to a polynucleotide encoding SEQ ID NO:6/SEQ ID NO:5, classified in Class 536, subclass 23.1.

Group 52. Claims 27-29 are drawn to SEQ ID NO:2, classified in Class 530, subclass 350.

Group 53. Claims 27-29 are drawn to SEQ ID NO:4, classified in Class 530, subclass 350.

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Group 54. Claims 27-29 are drawn to SEQ ID NO:6, classified in Class 530, subclass 350.

Group 55. Claims 33-36 are drawn to a method of identifying a compound that modulates the activity of SEQ ID NO:2, classified in Class 435, subclass 4.

Group 56. Claims 33-36 are drawn to a method of identifying a compound that modulates the activity of SEQ ID NO:4, classified in Class 435, subclass 4.

Group 57. Claims 33-36 are drawn to a method of identifying a compound that modulates the activity of SEQ ID NO:6, classified in Class 435, subclass 4.

15. Claims 37 and 40, as drawn to inhibitor/antibody against SEQ ID NO:2 links inventions 55-58. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 37/40. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of

35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 55. Claims 37-43 are drawn to a method of treatment of prostate cancer cells comprising administering an agent that modulates SEQ ID NO:2 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 56. Claims 37-43 are drawn to a method of treatment of breast cancer cells comprising administering an agent that modulates SEQ ID NO:2 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 57. Claims 37-43 are drawn to a method of treatment of lung cancer cells comprising administering an agent that modulates SEQ ID NO:2 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 58. Claims 37-43 are drawn to a method of treatment of ovarian cancer cells comprising administering an agent that modulates SEQ ID NO:2 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

16. Claims 37/40 as drawn to SEQ ID NO:4 links inventions 59-62. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 37/. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s)

depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 59. Claims 37-43 are drawn to a method of treatment of prostate cancer cells comprising administering an agent that modulates SEQ ID NO:4 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 60. Claims 37-43 are drawn to a method of treatment of breast cancer cells comprising administering an agent that modulates SEQ ID NO:4 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 61. Claims 37-43 are drawn to a method of treatment of lung cancer cells comprising administering an agent that modulates SEQ ID NO:4 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 62. Claims 37-43 are drawn to a method of treatment of ovarian cancer cells comprising administering an agent that modulates SEQ ID NO:4 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

17. Claim 37/40 as it is drawn to SEQ ID NO:6 links inventions 63-66. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 37/40. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group 63. Claims 37-43 are drawn to a method of treatment of prostate cancer cells comprising administering an agent that modulates SEQ ID NO:6 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 64. Claims 37-43 are drawn to a method of treatment of breast cancer cells comprising administering an agent that modulates SEQ ID NO:6 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 65. Claims 37-43 are drawn to a method of treatment of lung cancer cells comprising administering an agent that modulates SEQ ID NO:6 or a

variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

Group 66. Claims 37-43 are drawn to a method of treatment of ovarian cancer cells comprising administering an agent that modulates SEQ ID NO:6 or a variant thereof, classified in Class 514, subclass 2+, Class 424, subclass 130.1.

18. The inventions are distinct, each from the other because of the following reasons:

Inventions 49-54 as disclosed are biologically and chemically distinct, unrelated in structure and function, made by and used in different methods and are therefore distinct inventions.

Inventions 1-48. 55-66 are materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success.

he inventions of Groups 49-51 and 1-12/25-36 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polynucleotide product as claimed can be used in a materially different process such as producing a polypeptide.

The inventions of Groups 52-54 and 13-24, 37-48, 55-66 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (I) the process for using the

product as claimed can be practiced with another materially different product or (ii) the product as claimed can be used in a materially different process of using that product [see *MPEP* § 806.05(h)]. In the instant case the polypeptide product as claimed can be used in a materially different process such as the production of anti-polypeptide antibodies.

The inventions of Groups 51-53 and 13-24, 37-48, 55-66 are not at all related because the methods of Groups 13-24, 37-48, 55-66 do not use the nucleic acid product of Groups 51-53.

The inventions of Groups 54-56 and 1-12/25-36 are not at all related because the methods of Groups -12/25-36 do not use the nucleic acid product of Groups 54-56.

19. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, restriction for examination purposes as indicated is proper.

20. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time

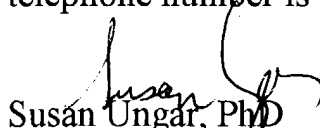
any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

22. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The fax phone number for this Art Unit is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Susan Ungar, PhD
Primary Patent Examiner
September 13, 2004